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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/960,256	09/20/2001	Jamie M. Grooms	RTI-128R	4334

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EXAMINER

WITZ, JEAN C

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 09/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/960,256

Applicant(s)

GROOMS ET AL.

Examiner

Jean C. Witz

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 13-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 13 and 14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. In response to the outstanding restriction requirement, Applicants point out that claim 9 is not drawn to a composition, but instead is drawn to a method step dependent upon claim 1. The restriction requirement contained a typographical error, since the composition was present in claim 3; however, in order to advance prosecution, the restriction requirement has been withdrawn and all claims present in the application will be examined. Claims 1-9 and 13-34 are present for examination.

Claim Rejections - 35 USC § 112

2. Claim 18 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of process collagen-based tissue prior to implantation wherein said tissue is bone, fibrous connective tissue, cartilage, dura, pericardia, heart valves, veins, arteries, dermis and glandular tissue, does not reasonably provide enablement for a method of process collagen-based tissue prior to implantation wherein said tissue is neural tissue, muscle or adipose tissue. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

While the specification identifies neural tissue and muscle tissue as tissue to be processed by the claimed method, there exist no working examples in the specification that such tissue has been so processed for implantation. While compliance with the

enablement requirement of 35 U.S.C. 112, first paragraph, does not turn on whether an example is disclosed, lack of a working example, however, is a factor to be considered, especially in a case involving an unpredictable art. The amount of guidance or direction needed to enable the invention is inversely related to the amount of knowledge in the state of the art as well as the predictability in the art. In *re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). The “amount of guidance or direction” refers to that information in the application, as originally filed, that teaches exactly how to make or use the invention. The more that is known in the prior art about the nature of the invention, how to make, and how to use the invention, and the more predictable the art is, the less information needs to be explicitly stated in the specification. In contrast, if little is known in the prior art about the nature of the invention and the art is unpredictable, the specification would need more detail as to how to make and use the invention in order to be enabling. The “predictability or lack thereof” in the art refers to the ability of one skilled in the art to extrapolate the disclosed or known results to the claimed invention. If one skilled in the art can readily anticipate the effect of a change within the subject matter to which the claimed invention pertains, then there is predictability in the art. On the other hand, if one skilled in the art cannot readily anticipate the effect of a change within the subject matter to which that claimed invention pertains, then there is lack of predictability in the art. Accordingly, what is known in the art provides evidence as to the question of predictability.

While connective tissue predominantly comprises a non-living matrix component (of which collagen is a component) and while organs and joints, defined as discrete

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structures composed of at least two tissue types wherein at least one of them is a connective tissue, both neural tissue and muscle tissue are comprised almost entirely of neural cells and muscle cells and are not considered "collagen-based tissue" as defined in the prior art. There is little extracellular matrix, but has mainly basement membrane-like components. Therefore, it would be expected that any decellularization step would leave little definable matrix component and there is no disclosure as to how this matrix component could be further used. Further, there is no disclosure of recellularization of the implant and its ultimate use. While connective tissue cells, such as fibroblasts, chondroblasts and osteoblasts, are known to be used to repopulate collagen-based connective tissue implants, use of neural cells or muscle cells is not conventional and also fraught with unpredictability. As a result, the specification provides insufficient enablement for the use of these tissues in the method as claimed.

3. Claim 18 and 32 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 18 fails to particularly point out and distinctly claim the subject of Applicants' invention. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. &

Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 18 recites the broad recitation "fibrous connective tissue", and the claim also recites "including tendons and ligaments" which is the narrower statement of the range/limitation.

Further, regarding claim 18, the phrase "other vasculature" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "other"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d).

Claim 32 is listed as "currently amended" and as amended consists only of the phrase "The method of claim 26"; all other words originally present of the claim are indicated as deleted. Therefore, the claim fails to particularly and distinctly recited that which Applicants consider to be their invention.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-4 and 8 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by U.S. Patent 5,843,182 to Goldstein.
6. Claims 1-4 and 8 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by U.S. Patent 5,336,616 to Livesey et al.
7. Claims 1-4 and 8 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by U.S. Patent 5,916,265 to Hu.
8. Claims 1-4 and 8, 13, 18, and 19 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by U.S. Patent 5,607,476 to Prewett et al.
9. Claims 1-4, and 8 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by U.S. Patent 6,376,244 to Atala.
10. Claims 1-5 and 7-9 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by U.S. Patent 6,482,584 to Mills et al.
11. Claims 1-5, 7-31, 33-34 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by published U.S. Application 2002/0072806 to Buskirk et al.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,607,476 to Prewett et al.

U.S. Patent 5,607,476 to Prewett et al. disclose that benzalkonium chloride is conventionally used to treat collagen-based tissues prior to implantation. Absent objective evidence to the contrary, optimization of a conventional ingredient used in a conventional manner is deemed well within the skill of the practitioner.

15. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,843,182 to Goldstein.

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The claim recites that the collagen-based tissue is a trachea. Goldstein teaches that any collagen-based tissue structures may be processed in the manner claimed. Since trachea is inherently a collagen-based tissue, it would have been well within the skill of one of ordinary skill in the art at the time the invention was made to select the trachea.

16. Claims 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Atala and Livesey et al. in view of Prewett et al.

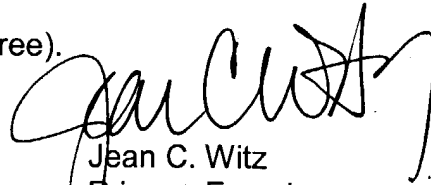
Prewett et al. teaches that connective tissue implants are conventionally treated to with benzalkonium chloride to disinfect the tissue. It would have been obvious to one of ordinary skill in the art at the time the invention was made to treat other conventional connective tissue implants such as those disclosed by Atala and those disclosed by Livesey et al. in order to disinfect them. One of ordinary skill in the art would have a reasonable expectation that if benzalkonium chloride would disinfect collagen-based tissues, such activity would be similar with other conventional collagen-based tissues.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jean C. Witz whose telephone number is (571) 272-0927. The examiner can normally be reached on 6:30 a.m. to 4:00 p.m. M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jean C. Witz
Primary Examiner
Art Unit 1651